Remarks

Claim 19 has been amended to an independent claim format by explicitly incorporating the features of claim 14, from which claim 19 was dependent. No prohibited new matter has been introduced by the amendment. Claim 18 has been cancelled without prejudice or disclaimer of the encompassed subject matter.

1. Rejection under 35 U.S.C. 101

Claims 14, 16 and 18-21 are rejected for allegedly lacking patentable utility for the reasons asserted on pages 2-5 of the Office Action. The Examiner's basic argument against utility appears to be that the test data described in Applicant's specification was based on comparison to a "non-control" – *i.e.*, a compound (warfarin) not known to be a cholesterol-lowering agent.

Applicant submits that Example 1 as described in Applicant's as-filed specification provides clear evidence that the administration of ximelagatran to human subjects leads to statistically significant reductions in cholesterol, triglyceride and LDL serum concentrations, together with a statistically significant increase in HDL serum concentration in those subjects in comparison with a control substance (warfarin) which has no such cholesterol-lowering properties. Applicant considers the generated data to be sufficient to demonstrate the potential utility of ximelagatran and related compounds in the cholesterol-lowering therapies as claimed.

The Examiner has declared the test in Example 1 to be flawed by virtue of the use of a control substance which does not have any known cholesterol-lowering properties. By taking this stance, the Examiner is setting an arbitrary standard against which he considers that the compounds must be proven to be effective. Applicant submits that it is not scientifically justifiable for the Examiner to declare that the cholesterol-lowering effect observed in the described tests is insufficient to demonstrate practical utility. Indeed, a control can be (and usually is) a placebo, and showing that a low molecular weight thrombin inhibitor has an effect against any control is sufficient to demonstrate that thrombin inhibitor's effectiveness. The Examiner's implication that the claimed compounds must be better than other known

cholesterol-lowering drugs is most certainly not the criteria for determining whether an invention is patentable.

Further, the Examiner's analogy regarding Michael Jordan's potential as a baseball player is flawed. The Examiner states that Michael Jordan is considered to have measurable ability as a baseball player, although this ability is not considered sufficient for him to be a Major League baseball player. Here again, the Examiner has set up an arbitrary standard by assessing Michael Jordan's ability against that of a Major League baseball player. He has overlooked the fact that Michael Jordan has a measurable ability as an ordinary baseball player and would therefore realistically be considered able to play baseball. Whether or not he is realistically able to compete in a Major League baseball game is irrelevant to the fact that he can play baseball.

Continuing the analog into the field of medicinal chemistry, the measurable utility of a compound against any control should be sufficient to show that the compound exhibits the desired medical effect. To illustrate this point, the Examiner's attention is drawn to the following hypothetical situation. Suppose that the analgesic properties of acetaminophen (known, at least, as an antipyretic) had not been discovered, while opiates such as morphine were well known as having utility in pain-relieving treatments. Suppose further, that the analgesic properties of acetaminophen are subsequently discovered by a medicinal chemist. If it were only demonstrated that acetaminophen possessed analgesic properties statistically significantly better than other antipyretic drugs which have no known analgesic properties, would the Examiner deny the utility of acetaminophen as an analgesic? Would utility only be acknowledged if acetaminophen were proven to be as potent as known analgesics such as morphine? Clearly, such an approach would exclude from patentability the use, in pain relief therapies, of one of the most widely employed drugs ever discovered.

In view of the above, Applicant submits that the demonstration of a measurable and statistically significant cholesterol-lowering effect for ximelagatran in Example 1 should be sufficient for the subject matter of the application to be considered as having the utility claimed. Applicant therefore respectfully requests that this rejection be withdrawn.

2. Rejection under 35 U.S.C. 112, second paragraph

Claims 18-21 are rejected because the Examiner asserts that there is insufficient antecedent basis for the term "prodrug" since the term has been deleted from the base claim 14. However, the Examiner suggests amending claims 19-21 into base claim 14.

To expedite prosecution of the application, Applicant has cancelled claim 18 without prejudice or disclaimer of the encompassed subject matter. Further, Applicant has amended claim 19 to an independent claim format by explicitly incorporating the features of base claim 14.

In view of the above amendments and cancellations, Applicant respectfully requests that this rejection be withdrawn.

3. Conclusion

The foregoing amendments and remarks are made to place the application in a condition for allowance. Applicant respectfully requests reconsideration and the timely allowance of the pending claims. The Examiner is invited to telephone the undersigned to advance prosecution of the application.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted,
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